



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

September 28, 2015

Jamie Staley
U.S. Registration Manager
Pioneer Hi-Bred International, Inc.
7100 NW 62nd Avenue
Johnston, IA 50131

Subject: Non-PRIA (Pesticide Registration Improvement Act) Labeling Amendment –To extend expiration date, update the product name, revise the ingredient statement and make other minor revisions to the label
Product Name: Herculex[®] XTRA Insect Protection
EPA Registration Number: 29964-5
Application Date: June 26, 2015
OPP Decision Number: 509316

Dear Mr. Staley:

The amended labeling referred to above, submitted in connection with registration under Sec. 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable and the expiration date of the registration has been hereby extended to January 31, 2016.

This approval does not affect any terms or conditions that were previously imposed on this registration. You continue to be subject to existing terms or conditions on your registration and any deadlines connected with it.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling.

Should you wish to add/retain a reference to your company's website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by the U.S. Environmental Protection Agency (EPA). If the website is false or misleading, the product will be considered to be misbranded and sale or distribution of the product is unlawful under FIFRA section 12(a)(1)(E). 40 CFR § 156.10(a)(5) lists examples of statements the EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the EPA find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA-approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance Assurance.

Page 2 of 2

EPA Reg. No. 29964-5

OPP Decision No. 509316

Your release for shipment of this product constitutes acceptance of these terms. If these terms are not complied with, this registration will be subject to cancellation in accordance with FIFRA section 6.

If you have any questions, please contact Ann Sibold of my team by phone at (703) 305-6502 or via email at sibold.ann@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read 'Alan Reynolds', with a stylized flourish at the end.

Alan Reynolds, Team Leader
Microbial Pesticide Branch
Biopesticides and Pollution
Prevention Division (7511P)
Office of Pesticide Programs

Enclosure

Herculex[®]* XTRA Insect Protection
(OECD Unique Identifier: DAS-Ø15Ø7-1xDAS-59122-7)

Active Ingredients:

Bacillus thuringiensis Cry1F protein and the genetic material (plasmid insert PHI8999A) necessary for its production in corn event DAS-Ø15Ø7-1 ≤0.00174%**

Bacillus thuringiensis Cry34Ab1 protein and the genetic material (PHP17662 T-DNA) necessary for its production in corn event DAS-59122-7 ≤0.01684%**

Bacillus thuringiensis Cry35Ab1 protein and the genetic material (PHP17662 T-DNA) necessary for its production in corn event DAS-59122-7 ≤0.00676%**

Other Ingredient:

Phosphinothricin acetyltransferase (PAT) protein and the genetic material (plasmid insert PHI8999A and PHP17662 T-DNA) necessary for its production in corn events DAS-Ø15Ø7-1 and DAS-59122-7 ≤0.00151%**

**Percentage (wt/wt) on a dry wt. basis for whole plant (forage)

KEEP OUT OF REACH OF CHILDREN

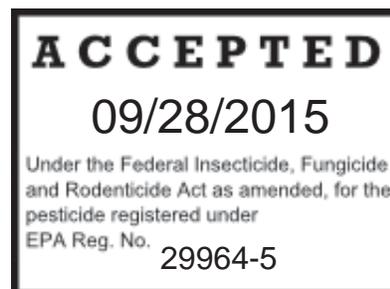
CAUTION

NET CONTENTS _____

EPA REGISTRATION NUMBER: 29964-5

EPA ESTABLISHMENT NUMBER: 029964-IA-001

Pioneer Hi-Bred International, Inc.
7300 NW 62nd Avenue
Johnston, IA 50131



* Herculex[®] XTRA Insect Protection technology by Dow AgroSciences and Pioneer Hi-Bred. Herculex[®] is a trademark of Dow AgroSciences LLC.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling.

This plant-incorporated protectant (PIP) may be combined through conventional breeding with other registered plant-incorporated protectants that are similarly approved for use in combination, through conventional breeding, with other registered plant-incorporated protectants to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits.

The plant-incorporated protectant must be used as specified in the terms and conditions of the registration.

Herculex[®] XTRA (Herculex[®] XTRA) combines the insect protection features of Herculex[®] I Insect Protection and Herculex[®] RW in the same corn hybrid (inbred). Herculex[®] XTRA hybrids protect corn crops from leaf, stalk and ear damage caused by Lepidopteran corn pests such as the European corn borer and root damage caused by corn rootworm larvae. In order to minimize the risk of the corn pests developing resistance to Herculex[®] XTRA corn, an insect resistance management plan must be implemented.

Routine applications of insecticides to control European corn borer and corn rootworm are unnecessary for corn containing *B.t.a.* delta-endotoxin Cry1F protein and *B.t.* Cry34/35Ab1 ICPs.

INSECT RESISTANCE MANAGEMENT

These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn up to a total of 20,000 acres per county and up to a combined United States (U.S.) total of 250,000 acres per plant-incorporated protectant (PIP) active ingredient per registrant per year.

Seed bags or bag tags will prominently display the refuge size requirement using graphics accompanied by text. For seed distributed outside cotton-growing areas the information will indicate that the product requires a 20% structured refuge for lepidopteran pests, and for seed distributed within cotton-growing areas the information will indicate that the product requires a 50% structured refuge for lepidopteran pests. For all seed, the information will indicate that the product requires a 20% structured refuge for corn rootworm.

Growers are instructed to read information on insect resistance management. The following information regarding refuge placement for commercial production must be included in the Grower Guide.

The use of Herculex[®] XTRA requires accompanying refuge corn for both the Cry1F and Cry34/35Ab1 components that meets the requirements of the individual traits, described below. The refuge for both traits may be combined by planting non-*Bacillus thuringiensis* (*Bt*) corn as the refuge (see C. below), or the refuge for each trait may be planted separately (see A. and B. below).

For the separate refuges, corn rootworm-resistant *Bt* corn (e.g., Herculex[®] RW) may be planted in the lepidopteran refuge for the Cry1F component and lepidopteran-resistant *Bt* corn (e.g., Herculex[®] I) may be planted in the corn rootworm refuge for the Cry34/35Ab1 component. Depending on cropping practices, pest problems, and pest management options employed on any given farm, growers may need to choose different refuge arrangements for different fields. Two refuge blocks (one for rootworm, one for Lepidoptera) can be planted within one field, or strips can be used for either refuge. Alternatively, a block of Herculex[®] RW can serve as an in-field lepidopteran refuge for one field planted to Herculex[®] XTRA and an external lepidopteran refuge for separate fields planted to Herculex[®] XTRA, while the rootworm refuge is planted as Herculex[®] I in an external adjacent field. In all options, size and management of each individual refuge must be followed as described in A. and B. below.

Other refuge designs and combinations are permissible as long as, in all cases, the size and management of each refuge are described in A., B., and C. below.

A. Lepidopteran refuge for the Cry1F component.

1. *Refuge size, Corn-Growing Areas* (= Corn Belt and other non-corn/cotton-growing regions). The use of Herculex[®] XTRA requires an accompanying 20% refuge consisting of non-*Bt* corn or corn that is not a lepidopteran-protected *Bt* hybrid.
2. *Refuge size (Corn/Cotton-growing areas)*. ** The use of Herculex[®] XTRA requires an accompanying 50% refuge consisting of non-*Bt* corn or corn that is not a lepidopteran-protected *Bt* hybrid.
3. *Refuge location*.
 - The lepidopteran refuge can be planted in a separate field within a ½ mile of the Herculex[®] XTRA field.
 - The lepidopteran refuge can be planted within the Herculex[®] XTRA field as blocks (e.g. along the edges or headlands).
 - The lepidopteran refuge can be planted within the Herculex[®] XTRA field as strips across the field at least four (4) consecutive crop rows wide.
4. *Refuge management*.
 - Insecticide treatments for control of European corn borer, corn earworm, southwestern corn borer, and other lepidopteran pests listed on the label, grower guides, or other educational material may be applied only if economic thresholds are reached for one or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service Agents, crop consultants). Instructions to growers will specify that microbial *Bt* insecticides must not be applied to refuges consisting of non-*Bt* corn or corn that is not a lepidopteran-protected *Bt* hybrid.

** Cotton-growing areas consist of the following states: Alabama, Arkansas, Georgia, Florida, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman and Washita), Tennessee (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), Texas (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), Virginia (only the counties of Dinwiddie, Franklin City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey and Sussex) and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott and Stoddard).

B. Corn rootworm refuge for the Cry34/35Ab1 component.

1. *Refuge size*. The use of Herculex[®] XTRA corn requires an accompanying 20% refuge consisting of non-*Bt* corn or corn that is not a rootworm-protected *Bt* hybrid.
2. *Refuge location*. The rootworm refuge is required to be planted within or adjacent (e.g., across the road) to the Herculex[®] XTRA field.
3. *Refuge management options*. The rootworm refuge can be managed in such a way that there is little or no yield loss to rootworms, but must be managed in a way that it is sufficiently productive of susceptible rootworm adults.
 - The in-field rootworm refuge options must be planted as a single block or as a series of strips measuring at least four (4) consecutive crop rows wide.

- Seed mixtures of Herculex® XTRA and rootworm refuge corn are not permitted.
- If the rootworm refuge is planted on rotated ground, then Herculex® XTRA must also be planted on rotated ground.
- If the rootworm refuge is planted in continuous corn, the Herculex® XTRA field may be planted on either continuous or rotated land (option encouraged where WCRW rotation-resistant biotype may be present).
- Application of soil insecticide is permitted in the rootworm refuge.
- Seed treatment is permitted in the rootworm refuge, either at a rate for rootworm protection or at a rate for controlling secondary soil pests.
- If aerial insecticides are applied to the rootworm refuge for control of CRW adults, the same treatment must also be applied in the same time-frame to Herculex® XTRA.
- Pests other than adult corn rootworms can be treated on the rootworm refuge acres without treating the Herculex® XTRA acres only if treatment occurs when adult corn rootworms are not present or if a pesticide without activity against adult corn rootworms is used. Pests on the Herculex® XTRA acres can be treated as needed without having to treat the rootworm refuge.
- The rootworm refuge can be planted to any corn hybrid that does not express PIPs for rootworm control (e.g. lepidopteran-protected *Bt* corn, herbicide-tolerant corn, or conventional corn).
- The rootworm refuge and Herculex® XTRA should be sown on the same day, or with the shortest window possible between planting dates, to ensure that corn root development is similar among varieties.
- Growers are encouraged to plant the rootworm refuge in the same location each year, as it allows the rootworm population to remain high and the durability of the trait is extended. This option may be preferable to growers who wish to only think of their refuge design once and for growers who grow continuous corn. However, for those growers who need to employ crop rotation, a fixed refuge would be impractical.

C. For the combined refuge option (i.e., the lepidopteran refuge combined with the rootworm refuge by planting non-*Bt* corn), the refuge must be planted and managed such that it is consistent with the requirements of the two individual traits, as follows:

1. *Refuge size* shall be 20% in corn-growing areas and 50% in cotton-growing areas (see list of states labeled with “**“ under A).
2. *Refuge location.* The combined refuge is required to be planted within or adjacent (e.g., across the road) to the Herculex® XTRA field.
3. *Refuge management options.*
 - The in-field refuge options must be planted as a single block or as a series of strips measuring at least four (4) consecutive crop rows wide.
 - Seed mixtures of Herculex® XTRA and refuge corn are not permitted.
 - If the combined refuge is planted on rotated ground, then the Herculex® XTRA must also be planted on rotated ground.
 - If the combined refuge is planted on continuous corn, the Herculex® XTRA field may be planted on either continuous or rotated land (option encouraged where WCRW rotation-resistant biotype may be present).
 - Application of soil insecticide for corn rootworm control is permitted in the combined refuge.
 - Seed treatment is permitted in the combined refuge, either at a rate for rootworm protection or at a rate for controlling secondary soil pests.
 - If aerial insecticides are applied to the combined refuge for control of CRW adults, the same treatment must also be applied in the same timeframe to Herculex® XTRA.

- Insecticide treatments in the combined refuge for control of European corn borer, corn earworm, southwestern corn borer, and other lepidopteran pests listed on the label, grower guides, or other educational material may be applied only if economic thresholds are reached for one or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service Agents, crop consultants). These pests can be treated with CRW-labeled insecticide on the combined refuge acres without treating the Herculex[®] XTRA acres only if treatment occurs when adult corn rootworms are not present. Instructions to growers will specify that microbial *Bt* insecticides must not be applied to the combined refuges.
- Pests other than adult corn rootworms can be treated with CRW-labeled insecticide on the combined refuge acres without treating the Herculex[®] XTRA acres only if treatment occurs when adults corn rootworms are not present. Pests on the Herculex[®] XTRA acres can be treated as needed without having to treat the refuge.
- The combined refuge can be planted to any corn hybrid that does not express PIPs for lepidopteran or rootworm control (i.e. herbicide-tolerant corn or conventional corn).
- The combined refuge and Herculex[®] XTRA should be sown on the same day, or with the shortest window possible between planting dates, to ensure that corn root development is similar among varieties.

Use Pattern

Crop	Pests
Field corn	black cutworm corn earworm European corn borer fall armyworm lesser corn stalk borer southern corn stalk borer southwestern corn borer sugarcane borer western bean cutworm western corn rootworm northern corn rootworm Mexican corn rootworm